PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 11533PC2-ABS/AKB	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International Application No. **PCT/AU2003/001467**	International Filing Date *(day/month/year)* 6 November 2003	Priority Date *(day/month/year)* 6 November 2002
International Patent Classification (IPC) or national classification and IPC **Int. Cl.**[7] A61K 38/17, A61P 37/06		
Applicant CBIO LIMITED et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

   [X] This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 1 sheet(s).

3. This report contains indications relating to the following items:

   - I [X] Basis of the report
   - II [ ] Priority
   - III [ ] Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV [ ] Lack of unity of invention
   - V [X] Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI [ ] Certain documents cited
   - VII [ ] Certain defects in the international application
   - VIII [ ] Certain observations on the international application

Date of submission of the demand 30 April 2004	Date of completion of the report 7 April 2005
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer ARATI SARDANA Telephone No. (02) 6283 2627

INTERNATIONAL PR[redacted]INARY EXAMINATION REPORT

[redacted]nternational application No.
PCT/AU2003/001467

I. Basis of the report

1. With regard to the **elements** of the international application:*

☐ the international application as originally filed.

☒ the description, pages **1-31 and 36** as originally filed,
pages , filed with the demand,
pages , received on with the letter of

☒ the claims, pages **32, 33 and 35** as originally filed,
pages , as amended (together with any statement) under Article 19,
pages , filed with the demand,
pages **34** received on **7 February 2005** with the letter of **7 February 2005**

☒ the drawings, pages **1/4-4/4** as originally filed,
pages , filed with the demand,
pages , received on with the letter of

☐ the sequence listing part of the description:
pages , as originally filed
pages , filed with the demand
pages , received on with the letter of

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages

☐ the claims, Nos.

☐ the drawings, sheets/fig.

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report*

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 1-29	YES
	Claims	NO
Inventive step (IS)	Claims 1-19 and 25-28	YES
	Claims 20-24 and 29	NO
Industrial applicability (IA)	Claims 1-29	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

CITATIONS:

D1: WO 02/040038 A

D2: Rizzo Monica et al. **"Increased Expression of HDJ-2 (Heat Shock Protein 40) and Heat Shock Protein 70 in Biopsy Specimens of Transplanted Human Lungs"** The Journal of Heart and Lung Transplantation, Vol. 17, No. 3, (March 1998), pg. 241-9.

D3: Chaouat G. "Immunosuppression Precoce et implantation" **CONTRACEPTION, FERTILITE, SEXUALITE, Vol. 23, No. 10, (October 1995), pg. 617-21 Ref: 58**

D2 discloses an increased expression of Heat Shock proteins 40 and 70 in lung transplant recipients undergoing rejection. Heat Shock protein Hsp 70 was a more sensitive, although less specific, predictor of rejection than Hsp 40.

D3 reviews antigenic status of the embryo and embryo rejection by the maternal immune system at implantation stage. The existence of Early pregnancy factor and immunoregulatory properties of tau interferons, interleukin 10 and TH1/Th2 balance concept.

The disclosure of D2 or D3 does not deprive present claims of their novelty or inventive step.

EXPLANATION:

NOVELTY (N) Claims 1-29:

D1 discloses the use of heat shock protein Chaperonin 10 (Cpn 10) in the treatment of allergic conditions such as cancer, asthma, rhinitis/hay fever, eczema, anaphylaxis and/or conditions typified by a T helper lymphocyte (TH2)-type immune response. D1 is directed to a pharmaceutical composition comprising cpn 10. D1 further discloses that cpn 10 stimulates the production of specific cytokines such as interleukin 10 (IL-10) and tumor necrosis factor α (TNFα).

In light of the response and amendments of 7 February 2005 claims 1-29 are novel.

Continued in supplemental Box I

Supplemental Box I

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of V

INVENTIVE STEP (IS) Claims 20-24 and 29:

The Attorney has argued that WO 02/040038 discloses a use of bacterial Chaperonin 10 (Cpn10) and that mammalian Cpn10 used in the present invention exhibits different physiological and immunological effects in animals.

The above argument is not persuasive because in both the present invention and in the citation Cpn10 stimulates or induces the production of IL-10. Therefore using Cpn10 from a different source to induce the production of a same protein IL-10 would be within the knowledge of the skilled addressee and will not involve an inventive step. Therefore claims 20-23 lack an inventive step.

Claims 24 and 29 lack an inventive step in light of the disclosure of D1 because it would be routine for the skilled person to obtain a mammalian Cpn 10 having a specific amino acid sequence for formulating a pharmaceutical composition. Therefore claims 24 and 29 lack an inventive step.

inhibit, suppress or otherwise reduce production of TNFα in said animal.

17. A method of inhibiting, suppressing or otherwise reducing TNFα production by one or more cells, tissues or organs obtained from an animal including the step of administering to said cells, tissues or organs a pharmaceutically-effective amount of cpn10 or derivative of cpn10 to thereby inhibit production of TNFα by said animal.

18. The method of claim 16 or claim 17 wherein said animal is a mammal.

19. The method of claim 18 wherein said mammal is a human.

20. A method of inducing, augmenting or otherwise increasing IL-10 production in an animal including the step of administering to said animal a pharmaceutically-effective amount of cpn10 or derivative of cpn10 to thereby induce, augment or otherwise increase production of IL-10 in said animal.

21. A method of inducing, augmenting or otherwise increasing TNFα production by one or more cells, tissues or organs obtained from an animal including the step of administering to said cells, tissues or organs a pharmaceutically-effective amount of cpn10 or derivative of cpn10 to thereby induce production of IL-10 by said animal.

22. The method of claim 20 or claim 21 wherein said animal is a mammal.

23. The method of claim 22 wherein said mammal is a human.

24. A pharmaceutical composition for use according to the method of claims 1, 16 or 17 comprising a pharmaceutically-effective amount of cpn10 or a derivative of cpn10, and a pharmaceutically-acceptable carrier, excipient or diluent.

25. The pharmaceutical composition of claim 24 further comprising at least